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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/512,829	GARVEY ET AL.	
	Examiner	Art Unit	
	Deepak R Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41,50,51,59,60,64,66,68,79-111,113-115,117 and 118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41,50,51,59,60,64,66,68,79-111,113-115,117 and 118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 36-41, 50-51, 59-60, 64, 66, 68, 79-111, 113-115 and 117-118 are pending in this application.

This office action is in response to the amendment filed on March 2, 2004.

Upon reconsideration, the finality of the previous office action has been withdrawn in view of the new grounds of rejection.

Election/Restrictions

Applicant's election of the species of **lansoprazole** as the proton pump inhibitor and **S-nitrosoglutathione** as the compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or a substrate of nitric oxide synthase, is acknowledged. As the respective species were found in the prior art, the examination was limited to the elected species. MPEP § 803.02. The remaining proton pump inhibitor compounds and NO donating compounds from the claims under consideration (i.e., claims 36-41, 50-51, 59-60, 64, 66, 68, 85-86, 87-88, 89, 94, 101-105, 106-110, 111, 113-114, 115, 117-118) are additionally withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-60, 87-88, 89, 94, 36-41, 79-84, 90-93 and 95-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of a gastrointestinal disorder, does not reasonably provide enablement for preventing a gastrointestinal disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The scope of the above method claims is not adequately enabled solely based on proton pump inhibitory activity provided in the specification. The instant claims are drawn to 'a method of .... **preventing** gastrointestinal disorders' and therefore, the instant claim language embraces disorders not only for the treatment, but for "prevention" which is not remotely enabled. The instant compounds are disclosed have proton pump inhibitory activity and it is recited that the instant compounds are useful in the "prevention" of gastrointestinal diseases for which applicants provide no competent evidence. "To prevent" actually means *to anticipate* or *counter in advance, to keep from happening etc.* (as per Websters II Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. The only test example 4 in the specification provides assay measuring the gastric lesion activity, however, it is inconceivable as to how the claimed compositions, not only treat but also "prevent" a myriad of diseases with different etiologies. Further, there is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims are seen to encompass methods for treating or preventing gastrointestinal disorders by administering a proton pump inhibitor such as lansoprazole and a compound that donates, transfers or releases nitric oxide such as S-nitrosoglutathione. Gastrointestinal disorders as described in the instant specification (and as

recited in claims), is seen to include the conditions Crohn's disease, ulcerative colitis, peptic ulcer, colitis, etc.

The nature of the invention

Currently, there are no known agents with the chemotherapeutic efficacy to prevent Crohn's disease, ulcerative colitis, diverticulitis, etc. The art does not disclose an active agent or combination of active agents which is recognized to prevent the conditions cited supra. The prior art does not teach or disclose a treatment modality wherein healthy subjects are administered an active agent or agent(s) and there is evidence that none of the associated symptoms or disease state characteristics are ever manifested. The disclosure does not direct the skilled artisan to art which satisfies the requirement for preventing a disease state associated with endothelial dysfunction selected from the group consisting of arteriosclerosis, diabetes, infections, inflammation, stroke and cardiovascular disease.

The state of the prior art

A search based on some of the diseases recited in the claims revealed the following statements that establishes there are no known agents or drugs that are administered in preventing these disorders, some of the relevant segments of information are provided here. The Merck Manual (Seventeenth Edition) provides that "The fundamental cause of Crohn's disease is unknown" and further, "No cure is known". "The cause of ulcerative colitis is unknown". "There is no known way to prevent Crohn's disease", see http://ehealthforum.com/health/subject74_187053_prevent.html. "Because the cause is unknown, prevention is also unknown", see http://www.nlm.nih.gov/medlineplus/ency/article/000250.htm. There was no conclusive evidence for the prevention of any of the claimed diseases.

The level of one of ordinary skill

The level of skill is that of a MD or PhD.

The level of predictability in the art

Since the art does not disclose any chemotherapeutic preventive agents, the skilled artisan would not predict, in the absence of proof to the contrary, that the active agent(s) instantly claimed are efficacious in preventing the claimed gastrointestinal disorders. The assertion of a broad application as set forth in the instant method claims necessarily requires evidence to support applicant's asserted methods. The examiner notes there are no known pharmaceutical agents recognized as **preventive** agents for the conditions claimed, and one of skill in this art could not predict, from the evidence of record, that the active agents asserted to be useful in the instantly claimed method, can indeed prevent Crohn's disease, ulcerative colitis, peptic ulcer, stress ulcer, bleeding peptic ulcer, duodenal ulcer, infectious enteritis, colitis, diverticulitis, gastric hyperacidity, dyspepsia, gastroparesis, Zollinger-Ellison syndrome, gastroesophageal reflux disease, a Helicobacter pylori associated disease, short bowel syndrome or a hypersecretory state associated with systemic mastocytosis or basophilic leukemia and hyperhistaminemia.

The amount of direction provided by the inventor

The examiner notes, there is not seen sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or references to same in the prior art to provide the skilled artisan with sufficient guidance to practice the instant preventive method. Prevention is seen to encompass administering the active agent to a baby or small child or healthy adult, and noting the fact that symptoms of the gastrointestinal disorders such as

Crohn's disease, ulcerative colitis, diverticultis, dyspepsia, etc. never manifest themselves. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of prevention of the gastrointestinal disorders of the claims.

The existence of working examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There is not seen in the disclosure, sufficient evidence to support applicant's claims of prevention. There is not seen sufficient working examples or data from references of the prior art providing a nexus between that which applicant asserts as proof of a method for preventing gastrointestinal conditions or extrapolation from the data and evidence currently provided on the record to support methods drawn to preventing any condition.

The quantity of experimentation needed to make or use the invention

The diagnosis of each of the disease is generally suggested by medical history and reports of endoscopy, cytology, X-ray, biopsy, etc. depending on the symptoms, signs and complications, which is essential to establish the dosage regimen for appropriate treatment or prevention. The disclosure does not provide any guidance towards the dosage regimen required to facilitate the prevention of the claimed disorders nor indicate competent technical references in the appropriate method of preventing.

Applicant's arguments presented in the amendment filed on December 13, 2001 have been fully considered but they were not deemed to be persuasive. Applicant relies on the WO

publications and US patent literature which broadly recite 'prevention' or 'prophylaxis' of the conditions. However, this is not seen to provide an enabling disclosure or sufficient guidance to a skilled worker in this field without undue experimentation, especially in view of the above analysis and discussion based on the state of the art seen in the prior art references. The references provide the therapeutic use of the disclosed compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41, 50-51, 59-60, 64, 66, 68, 79-111, 113-115 and 117-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In the instant method, claim(s) 50, 59, 64, 66, 68, 85, 87, 89 and 94 fail to particularly point out the identity of the active compound to be administered in the instantly claimed method. The current claim language is drawn to administering a compound which is not described structurally/ formulaically/nomenclatorially; however, the active compound's mode of action, function or effect (i.e., proton pump inhibition or donation or release of nitric oxide) requisite to practicing the claimed method is set forth. The claim is missing the critical element which is the particular or distinct identity of the active compound to be used in the claimed method. It is noted the claim is limited to what the administration of "a compound" is intended to accomplish rather than what the active compound actually represents as a chemical entity.

2. In the instant composition/kit, claim(s) 101, 106, 111 and 115 fail to particularly point out the identity of the component described as proton pump inhibitor or compound that induces the production of endogenous nitric oxide. The current claim language is drawn to an activity or desired property of a compound/composition. This language does not particularly or distinctly provide sufficient clarity regarding the structural/ formulaic/nomenclatorial identity of the chemical core applicants intend to represent as a component of the composition/kit articulated in the claim.
3. Claim 36 recites that "compound is a benzimidazole, a quinoline, ..." wherein the terms indicate unsubstituted moieties and therefore, the recitation is confusing. The specification however, discloses compounds carrying specific substituents (see e.g., formula (I) in page 17). The instant recitation of 'benzimidazole', 'quinoline', etc. is understood as an unsubstituted compound. If a substituted compound (such as those disclosed in the specification) are intended, then that should be indicated accordingly with appropriate notation such as "benzimidazolyl of formula", "quinolinyl of formula", etc. All of the examples provided for the proton pump inhibitors in the specification are substituted compounds having a benzimidazolyl, quinolinyl, etc. as the core structure. Neither the specification nor the references cited provide that 'benzimidazole', 'quinoline', etc. are also active proton pump inhibitors. The discrepancy is also found in claims 92, 104, 109, 113 and 117.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 50-51, 59-60, 64, 66, 85-86, 87-88, 89, 36-41, 79-84 and 90-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Nohara et al., U.S. Patent No. 4,628,098 or Depui et al., WO 97/25064 or WO 96/24375] and Stamler et al., U.S. Patent No. 5,380,758.

Nohara et al. (US'098), teaches benzimidazole compounds including lansoprazole that are useful in treating gastrointestinal disorders, see formula (I) in the reference and the specific compound in claim 10.

Depui et al. (WO'064) teaches proton pump inhibitors that are useful in the treatment of gastrointestinal disorders and exemplifies lansoprazole (see page 10, second compound). WO'064 teaches the combination of the proton pump inhibitor with a NSAID, which NSAID's include selective COX-2 inhibitors and NO releasing NSAID's (see page 13, lines 1-2) and

antacid formulations (see page 17, lines 7+), however, the reference does not exemplify a S-nitrosothiol.

Also, see WO'375 which discloses lansoprazole (page 8, third compound) and teaches the use of the proton pump inhibitor compounds in treatment of disorders associated with *Helecobacter pylori*. Further, WO'375 teaches that combination therapy of these diseases with bismuth compounds, see page 1, second paragraph.

Stamler et al., US'758 in the analogous art teaches S-nitrosothiols including S-nitrosoglutathione (see col. 10, line 36) that have gastrointestinal therapeutic activity (see col. 9, lines 34-47). Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of the above references because he would have had the reasonable expectation that the composition comprising the individual compounds of the references would have the same therapeutic activity as taught for each of the compounds. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant's arguments submitted in the previous responses have been fully considered but they were not deemed to be persuasive. Applicant first argues that independent claims 50 and 64 specifically refer to 'improving the gastroprotective properties', etc. of the proton pump inhibitor and the references do not disclose or suggest such methods. However, the references individually teach therapeutic administration of lansoprazole or S-nitrosoglutathione to a patient in need of such treatment. The instant claims also recite a method of administering the same compounds to the same patient population. The preamble language is not given any patentable weight as it does not add any life, meaning or vitality to the claim. The preamble of the instant

claims is purely a recitation of intended use. The essence of the actual steps of the invention is giving the two drugs to a patient needing the therapy. The preamble does not add any structural limitations to the claim. *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation").

Next, applicant argues that Stamler reference teaches the use of S-nitrosothiols for relaxing gastrointestinal smooth muscle and applicant's presently claimed methods are unrelated to such activity. However, Stamler clearly teaches the use of S-nitrosothiols in treating gastrointestinal diseases, see col. 9, lines 34+. Stamler teaches the therapeutic administration of S-nitrosothiol compounds in a method to achieve the benefit of treating gastrointestinal diseases, which is the same benefit sought in the instant claims. The specific recitation of improving various properties of the proton pump inhibitor in the preamble of the claim is not given any patentable weight because it does not add any structural limitations to the claimed method. The specific characteristic of 'improving gastroprotective properties' recited in the claims is an inherent effect of the combination of the two agents.

Applicant argues that the references are devoid of any suggestion to combine the proton pump inhibitor and NO donor. This is not found to be persuasive. The references individually teach administration of the compounds to achieve the same therapeutic benefit and therefore, there is sufficient motivation to one of ordinary skill in the art to combine the same.

Applicant submits that Depui reference teaches proton pump inhibitors in combination with NSAID compounds or an antacid formulation and their methods of use for treating

gastrointestinal disorders, but argues that the reference does not teach or suggest the use of compounds of the instant claims that donate, transfer or release nitric oxide. However, Stamler in analogous art teaches the use of such compounds in the treatment of gastrointestinal disorders and thus, the motivation to combine the references flows logically from their having been individually taught in the prior art.

Applicant lists the various diseases specifically recited in claim 59 and argues that 'there is no evidence of record of any relationship between Stamler's disclosed method and the claimed methods'. This is not found to be persuasive because Stamler clearly teaches the use of the compounds in treating gastrointestinal disorders which include those of the esophagus, duodenum, sigmoid colon, etc. (see col. 9, lines 34-47). The instant claims also recite **gastroesophageal** reflux disease, colitis (i.e., inflammation of the mucous membrane of the **colon**), **duodenal** ulcer, etc. which involve the specific target areas discussed in Stamler and applicant has not provided any evidence to the contrary.

Applicant argues that the references Nohara and WO 96/24375 do not disclose or suggest a method for 'decreasing or reversing gastrointestinal toxicity' etc. However, the references clearly teach therapeutic administration of lansoprazole in a method to achieve the benefit of treating gastrointestinal diseases, which is the same therapeutic benefit achieved in the instant claims. The preamble language is not given any patentable weight as it does not add any life, meaning or vitality to the claim. The preamble of the instant claims is purely a recitation of intended use. The essence of the actual steps of the invention is giving the two drugs to a patient needing the therapy. The preamble does not add any structural limitations to the claim.

2. Claims 68, 36-41 and 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al., WO 96/24375 and Stamler et al., U.S. Patent No. 5,380,758.

WO'375 discloses lansoprazole (page 8, third compound) and teaches the use of the proton pump inhibitor compounds in treatment of disorders associated with *Helicobacter pylori*. Further, WO'375 teaches that combination therapy of these diseases with bismuth compounds, see page 1, second paragraph. The reference also teaches the relationship between gastrointestinal disorders and infections due to *Helicobacter pylori*, see page 1.

Stamler et al., US'758 in the analogous art teaches S-nitrosothiols including S-nitrosoglutathione (see col. 10, line 36) that have gastrointestinal therapeutic activity (see col. 9, lines 34-47). Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of the above references because he would have had the reasonable expectation that the composition comprising the individual compounds of the references would have the same therapeutic activity as taught for each of the compounds. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant argues that WO'375 does not disclose or suggest the use of NO donors to treat *Helicobacter pylori* infections. However, the reference clearly teaches the use of proton pump inhibitors in a method of treating *Helicobacter* infections which include gastrointestinal disorders such as ulcers. Stamler teaches the use of NO donors such as S-nitrosoglutathione in the treatment of gastrointestinal disorders. Therefore, there is sufficient motivation to the skilled artisan to combine these teachings with Stamler as the references individually teach the use of the respective compounds for the treatment of gastrointestinal disorders.

3. Claims 101-111, 113-115 and 117-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Nohara et al., U.S. Patent No. 4,628,098 **or** Depui et al., WO 97/25064] in combination with Stamler et al., U.S. Patent No. 5,380,758.

Nohara et al. (US'098), teaches benzimidazole compounds including lansoprazole that are useful in treating gastrointestinal disorders, see formula (I) in the reference and the specific compound in claim 10. The reference teaches the use of the compounds specifically for antagonizing ulceration by inhibiting gastric acid secretion. The reference clearly indicates the use of the compound in treating suppurating lesion on an internal mucous surface of the body. Also, Depui et al. (WO'064), teaches proton pump inhibitors useful in the treatment of gastrointestinal disorders and exemplifies lansoprazole (see page 10, second compound). WO'064 teaches the combination of the proton pump inhibitor with a NSAID, which NSAID's include selective COX-2 inhibitors and NO releasing NSAID's (see page 13, lines 1-2) and antacid formulations (see page 17, lines 7+), however, the reference does not exemplify a S-nitrosothiol.

Stamler et al., US'758 in the analogous art teaches S-nitrosothiols including S-nitrosoglutathione (see col. 10, line 36) that are useful in the treatment of gastrointestinal disorders (see col. 9, lines 34-47) including those of the gastrointestinal tract, e.g., removal of foreign bodies, polyps or other lesions. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of the above references because he would have had the reasonable expectation that the composition comprising the individual compounds of the references would have the same therapeutic activity as taught for each of the compounds. [T]he

idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant argues that Nohara and Depui references do not provide any motivation or suggestion to use proton pump inhibitors in combination with NO donors. However, the references clearly teach the individual drugs in the treatment of gastrointestinal disorders as discussed above. Motivation to combine the references flows logically from their individual teachings of the use of lansoprazole and S-nitrosoglutathione as therapeutic agents for the treatment of gastrointestinal disorders.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Deepak Rao
Primary Examiner
Art Unit 1624

May 17, 2004